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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/450,511 11/30/99 ARAI

K P18214

007055 IM22/0716  
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RESTON VA 20191

EXAMINER

MAYES, M

ART UNIT

PAPER NUMBER

1734

DATE MAILED:

07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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## Office Action Summary

Application No.  
09/450,511

Applicant(s)

Arai et al.

Examiner

Curtis Mayes

Art Unit

1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-17 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19)  Notice of Informal Patent Application (PTO-152)

20)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

(1)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(2)

Claims 1, 4, 8 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson et al.

Ferguson et al. disclose a method of bonding ceramic casting cores comprising: preparing two green ceramic casting cores; preparing a ceramic-solvent mixture of the ceramic present in the cores; brushing the mixture onto the bond surface of each core; assembling the cores; and heating to 1230°C to sinter (col. 4, lines 4-34).

(3)

Claims 1, 4-6, 8, 10-12, 14, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 2-225382.

JP 2-225382 discloses a ceramic bonding method for biomaterial comprising: providing formed products of ceramic material such as apatite, tricalcium phosphate or calcium phosphate; providing a bonding material comprised of particle filler of the ceramic material of the formed

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products in an aqueous solution of water soluble polymer; using the bonding material to bond the formed products; and firing. JP '382 discloses that the particles have an average particle size of 0.1-15 microns and the firing can be at 1200°C (Abstract).

***Claim Rejections - 35 USC § 103***

(4)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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(5)

Claims 7, 9, 10, 13, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2-225382.

JP 2-225382 further discloses that 5 to 40wt% of the particle filler is added to the aqueous solution.

Providing the apatite in the formed products and the bonding material as hydroxyapatite, as claimed in Claims 7 and 13 would have been obvious to one of ordinary skill in the art as well known in that art of biomaterials as an apatite or calcium phosphate used as a biomaterial.

Providing the amount of particle filler in the bonding material in an amount in the range of 0.1 to 20vol%, as claimed in Claim 9, would have been obvious to one of ordinary skill in the art as JP '382 discloses adding 5 to 40wt% of the particle filler to the aqueous solution to form the bonding material.

Providing particles of average grain size in the range of 0.05 to 0.5 microns, as claimed in Claim 10, would have been obvious to one of ordinary skill in the art as JP '382 discloses using particle filler of average particle size in the range of 0.1 to 15 microns for the bonding material.

In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the reference JP 2-225382, such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

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When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

(6)

Claims 1-15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of JP 2-225382.

Kim et al. discloses a method of making a ceramic vertebrae prothesis comprising: providing a dried dense material to correspond to the center portion, providing a dried porous material to correspond to the circumferential portion; adhering the dried dense material to the dried porous material by an apatite slurry; and heating the assembly. The ceramic can be calcium phosphate of Ca/P ratio of 1.0 to 2.0 such as hydroxyapatite and the porous portion is made to have a porosity of 20-55%. Kim et al. disclose heating hydroxyapatite at 1000-1200°C to obtain a final product (col. 4, lines 18-38, col. 5, lines 1-6 and 13-26).

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JP 2-225382 teaches that to bond formed biomaterial products of ceramics such as apatite and calcium phosphate, a bonding material comprised of particle filler of the ceramic material of the formed products in an aqueous solution of water soluble polymer is used followed by firing at temperature such as 1200°C. JP '382 discloses that the particles have an average particle size of 0.1-15 microns and discloses that 5 to 40wt% of the particle filler is added to the aqueous solution (Abstract).

It would have been obvious to one of ordinary skill in the art to have adhered the dried dense and porous material of hydroxyapatite by an apatite slurry by using a slurry of hydroxyapatite followed by firing as JP '382 teaches that it is known in the art to bond ceramic products such as apatite and calcium phosphate using a slurry of particles of the same ceramic followed by firing of the adhered products at temperature such as 1200°C.

Providing the amount of particle filler in the bonding slurry in an amount in the range of 0.1 to 20vol%, as claimed in Claim 9, would have been obvious to one of ordinary skill in the art as JP '382 discloses adding 5 to 40wt% of the particle filler to the aqueous solution to form the bonding material.

Providing particles of average grain size in the range of 0.05 to 0.5 microns in the slurry, as claimed in Claim 10, would have been obvious to one of ordinary skill in the art as JP '382 discloses using particle filler of average particle size in the range of 0.1 to 15 microns for the bonding material.

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In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the combination of Kim et al. and JP 2-225382, such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

### *Conclusion*

(7)

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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(8)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Mayes, whose telephone number is (703) 308-1977. The examiner can normally be reached on Monday-Friday from 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino, can be reached on (703) 308-3853.

The Official FAX phone number for this Tech Center 1700 is (703) 305-7718.

The Unofficial Fax phone number is (703) 305-7115.

When filing a FAX in Tech Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with PTO that are not for entry into the file of the application. This will expedite processing of your papers.

The receptionist number for Tech Center 1700 is (703) 308-0661.

  
CURTIS MAYES  
PRIMARY EXAMINER  
Art Unit 1734  
July 13, 2001